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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,644	03/17/2005	Takeshi Ito	28361U	8336
20529	7590	11/30/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER ELLIS, SUEZU Y	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 11/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,644	ITO ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 25, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, line 5, delete "and rubber polymer" and insert --and a rubber polymer-- , for proper grammar.

Appropriate correction is required.

Claim Objections

Claim 6 is objected to because of the following informalities:

With respect to claim 6, claim 5 has the same limitations of claim 6, therefore claim 6 appears to be redundant with respect to claim 5.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terahara et al. (WO 02/38139). Hereinafter, US 2004/0028724 will be used as an English equivalent translation.

With respect to claim 1, Terahara et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and oxybutynin and/or a pharmaceutically acceptable salt thereof [0043], [0022], wherein the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group in the molecule and rubber polymer [0012], [0029], [0030]. Terahara et al. also discloses the acrylic polymer being 5-50% by weight and the rubber polymer being 20-40% by weight [0030], [0031]. Terahara et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4, as demonstrated in Example 1. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to

optimize the formation of the adhesive layer and sufficient skin permeability of the drug [0031]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 2, the modified Terahara et al. discloses the adhesive layer comprising 2-88% acrylic polymer [0031], 20-40% by weight rubber polymer [0030], and 10-50% by weight an alicyclic saturated hydrocarbon resin-based tackifier [0033]. More specifically, Terahara et al. demonstrates in Example 1, the adhesive layer comprising 5% by weight of an acrylic polymer, 20% by weight of a rubber polymer and 38% by weight of an alicyclic saturated hydrocarbon resin-based tackifier.

With respect to claim 3, the modified Terahara et al. discloses in Example 1, the weight ratio of total content of the acrylic polymer and the rubber polymer to content of the tackifier is from 1:1 to 1:3.

With respect to claim 4, the modified Terahara et al. discloses the acrylic polymer is a copolymer of polyarylate including butyl acrylate [0012], [0031].

With respect to claims 5 and 6, the modified Terahara et al. discloses the rubber polymer is at least one kind selected from styrene-isoprene-styrene block copolymer [0029].

With respect to claim 8, the modified Terahara et al. discloses the adhesive layer is compounded with oxybutynin hydrochloride [0022].

With respect to claims 9 and 10, the modified Terahara et al. discloses the adhesive agent further comprises an organic acid (carboxylic acid) that is citric acid or acetic acid [0017], [0024], [0025].

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232).

With respect to claim 1, Chono et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent (organic acid) and oxybutynin and/or a pharmaceutically acceptable salt thereof [0014], [0015] wherein the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group in the molecule and rubber polymer [0030]. Chono et al. also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 15-50% by weight [0031]. Chono et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 4-7, the modified Chono et al. discloses the acrylic polymer is copolymer of 2-ethylhexyl acrylate and vinyl acetate monomers, and the rubber polymer is styrene-isoprene-styrene block copolymer [0030], [0031].

With respect to claim 8, the modified Chono et al. discloses the adhesive layer is compounded with oxybutynin hydrochloride [0015].

With respect to claims 9 and 10, the modified Chono et al. discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 and 13 of copending Application No. 10/469,612 (amendment filed on 10/4/07) in view of Terahara et al. WO 02/38139 (US 2004/0028724 is used as an English equivalent translation).

This is a provisional obviousness-type double patenting rejection.

With respect to claim 1 of the current application, claims 1, 8 and 13 of Application No. 10/469,612 (amended claims filed 10/4/07) discloses:

(claim 1) **A patch comprising a support (functionally equivalent to a backing layer), and an adhesive layer laid on the support and containing an adhesive base (adhesive agent) and a drug, wherein said adhesive base contains an acrylic polymer substantially having no carboxyl group and no hydroxyl group in molecules thereof, wherein said polymer is at least one selected from the group consisting of: a 2-ethylhexyl acrylate N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate copolymer; an aminoalkylmethacrylate copolymer E; and a 2-ethylhexyl acrylate vinyl copolymer; and a rubber-based polymer.**

(claim 8) wherein **said drug is at least one selected from the group consisting of pergolide, pharmacologically acceptable salts of pergolide, oxybutynin, and pharmacologically acceptable salts of oxybutynin.**

(claim 13) wherein **said drug is selected from the group consisting of oxybutynin and pharmaceutically acceptable salts of oxybutynin.**

Claims 1, 8 and 13 of Application No. 10/469,612 fail to expressly disclose the weight ratio of content of the acrylic polymer to content of the rubber polymer being from

1:4 to 1:19. Terahara et al. discloses a patch comprising oxybutynin having an adhesive comprising of an acrylic polymer that is substantially free of both carboxyl and hydroxyl groups and a rubber polymer having a range of weight ratios, wherein the weight ratio can be 1:4 [0030], [0031]. It would have been obvious to one of ordinary skill in the art to modify the weight ratios in order to optimize the formation of the adhesive layer and sufficient skin permeability of the drug [0031]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Higo et al. (US 5,866,157) discloses a patch formulation containing oxybutynin hydrochloride, organic acids, and an adhesive comprising styrene-isoprene-styrene block copolymer or 2-ethylhexyl acrylate-vinyl acetate copolymer.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday)


Application/Control Number:
10/525,644
Art Unit: 1615

Page 9

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE


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